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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,326	11/17/2003	Samuel C. Wadsworth	5062CIP	7027

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,326	WADSWORTH ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, and 17-18, drawn to an isolated nucleic acid encoding a precursor GLP-1 comprising mammalian GLP-1 linked to a heterologous signal sequence, classified in class 435, subclass 6.

II. Claims 14 -16, drawn to an isolated polypeptide comprising mammalian GLP-1 linked to a heterologous signal sequence, classified in class 530, subclass 350.

III. Claims 19-22, drawn to a method of promoting insulin production in an individual comprising administering an effective amount of a nucleic acid encoding a precursor GLP-1, classified in class 424, subclass 9.1.

The inventions are distinct, each from each other because of the following reasons:

Inventions I, II are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polypeptide of Group II and the polynucleotide of Group I are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are

structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group I does not necessarily encode the polypeptide of Group II.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides is not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, a search of the nucleic acid molecules of Group I would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group II. As such, it would be burdensome to search the inventions of Groups I and II.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case nucleic acid of Group II can be used as a DNA probe in hybridization assays.

Searching the inventions I and III together would impose undue search burden. The inventions of II and III have a separate status in the art as shown by their different classifications. Moreover, the search for a nucleic acid DNA and the methods of promoting insulin production in an individual comprising administering a nucleic acid are not coextensive.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated. For example, the claimed method III does not recite the use of a polypeptide from Group II.

Furthermore, the inventions of Groups II and III require separate, distinct and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups II and III together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and separate search requirements, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the

limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-10. The inventions as they pertain to each of nucleic acid sequences of SEQ ID NOs: 1, 3, 5.....17, 19, encoding GLP-1, classification dependent

upon the nature of the inventions.

Each of the claimed nucleic acid sequences are composed of different purine and pyrimidine units and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching all of the above claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. Therefore, Applicant must choose 1 sequence from the Groups 11 -20 against which the search should be performed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 11-21.The inventions as they pertain to each amino acid sequences of SEQ ID NO: 12, 4, 6..... 18, 20 and 21, classification dependent upon the nature of the inventions.

Each of the claimed polypeptide sequences are composed of different amino acids and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching all of the above claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. Therefore, Applicant must choose 1 sequence from the Groups 1 -10 against which the search should be performed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

4. Claims 1-11 are drawn to a precursor GLP-1 comprising mammalian GLP-1 linked to a heterologous signal sequence. If the sequences 1-21 do not encompass the claimed limitation, Applicant is required to explicitly identify a single sequence encoding (i) GLP-1 molecule from claim 5, (ii) a leader sequence, (iii) a heterologous signal peptide sequence, and (iv) a cleavage site by its SEQ ID Number.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If Applicant selects Group I and II, one polynucleotide sequence from Groups 1-10 must also be chosen to be considered fully responsive. If Applicant selects Group III, one polypeptide sequence from Groups 11-21 must be chosen to be considered fully responsive. Applicant is advised that neither groups 1-10 nor 11-21 are species election requirements; rather each sequence of Groups 1-10 nor 11-21, is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
26 October 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER